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TITLE: A Placebo-Controlled Augmentation Trial of Prazosin for Combat Trauma PTSD

PRINCIPAL INVESTIGATOR: Murray Raskind

CONTRACTING ORGANIZATION: Seattle Institute for Biomedical/Clinical Research Inc.
Seattle, WA 98108

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14. ABSTRACT This study consists of a 14-week, two parallel group, randomized placebo controlled trial to evaluate the efficacy and tolerability of the alpha-1 adrenergic antagonist, prazosin, for reducing trauma nightmares and sleep disturbance and improving global function and sense of well-being, in 210 OIF and OEF combat-exposed returnees with PTSD and persistent trauma-related nightmares and disrupted sleep. A secondary aim is to assess efficacy of prazosin for reducing total PTSD symptoms, reducing symptoms of depression, improving quality of life, and reducing alcohol craving.				
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Introduction:

The objective of this randomized controlled trial (RCT) is to evaluate the efficacy and tolerability of the alpha-1 adrenergic antagonist prazosin compared to placebo for combat stress-related nightmares, sleep disturbance, and overall PTSD in combat trauma-exposed Service Members. The secondary objective of this trial is to assess the efficacy of prazosin for reducing total PTSD symptoms, reducing symptoms of depression, improving quality of life, and reducing alcohol use.

210 male and female returning troops from Operation Iraqi or Enduring Freedom (OIF/OEF), who manifest persistent combat stress-related nightmares and sleep disturbance in the context of PTSD, will be enrolled in the study. Participants undergo a flexible dose titration period followed by optimal dose treatment for a total of 15 weeks including the titration period. Primary and secondary outcome measures assess nightmares, sleep disturbance, PTSD severity by total CAPS score, depression, global function, and quality of life and are administered every four weeks. Data will be analyzed for significant differences among treatment groups using generalized estimating equations.

Body:

We have successfully launched and brought to the halfway enrollment point what (to our knowledge) is the first ever medication RCT for a behavioral disorder ever performed in US active duty combat Service Members. Our active outreach approach to recruitment continues successfully to attract volunteers for research participation, and also has provided support to the Psychiatry Service mission at Madigan Army Health Care System.

Key Research Accomplishments

- 89 soldiers have completed the protocol and 10 are currently randomized and participating.
- Recruitment continues to meet goals for study completion by end of 2012.
- All continuing regulatory reviews are up to date.

Reportable Outcomes

Pending

Conclusions

Pending

References

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Appendices

N/A

Supporting Data

Pending